Walker #25

United States Court of Appeals for the Federal Circuit

SOLICITOR

NOV 4 2005

U.S. PATENT & TRADEMARK OFFICE

04-1465

IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI

Judgment

ON APPEAL from the UNITED STATES PATENT AND TRADEMARK OFFICE, BOARD OF PATENT APPEALS AND INTERFERENCES

In CASE NO(S). 09/619,643

This CAUSE having been heard and considered, it is

ORDER and ADJUDGED:

AFFIRMED

CERTIFIED COPY
I HEREBY CERTIFY THIS DOCUMENT IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE.
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT
By: _____ Date: 10/31/05

ENTERED BY ORDER OF THE COURT

DATED SEP - 7 2005

Jan Horbaly

Jan Horbaly, Clerk

FILED
U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT
OCT 31 2005
JAN HORBALY
CLERK

ISSUED AS A MANDATE: OCT 31 2005

TR 14

United States Court of Appeals for the Federal Circuit

04-1465
(Serial No. 09/619,643)

IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI

Seth P. Waxman, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC, argued for appellants. With him on the brief were William F. Lee and Richard W. O'Neill, of Boston, Massachusetts; and William G. McElwain and Henry N. Wixon, of Washington, DC.

Stephen Walsh, Associate Solicitor, United States Patent and Trademark Office, of Arlington, Virginia, argued for the Director of the Patent and Trademark Office. With him on the brief were John M. Whealan, Solicitor, and Thomas W. Krause, Associate Solicitor.

Joseph A. Keyes, Jr., of Washington, DC, for amicus curiae Association of American Medical Colleges.

Marc S. Gold, of Washington, DC, for amicus curiae National Academy of Sciences.

Donald R. Stuart, of Indianapolis, Indiana, for amicus curiae Dow AgroSciences LLC. With him on the brief was Kenneth B. Ludwig.

Paula K. Davis, of Indianapolis, Indiana, for amicus curiae Eli Lilly and Company. With her on the brief were Steven P. Caltrider and James J. Kelley.

Michael C. Schiffer, of Irvine, California, for amicus curiae Baxter Healthcare Corporation.

Darrel C. Karl, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, for amicus curiae American College of Medical Genetics.

Jeffrey P. Kushan, Sidley Austin Brown & Wood, LLP, of Washington, DC, for amicus curiae Genentech, Inc. With him on the brief were Kathi A. Cover and David L. Fitzgerald.

George C. Yu, of Emeryville, California, for amicus curiae Affymetrix, Inc.

Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

United States Court of Appeals for the Federal Circuit

04-1465
(Serial No. 09/619,643)

IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI,

DECIDED: September 7, 2005

Before MICHEL, Chief Judge, RADER and BRYSON, Circuit Judges.

Opinion for the court filed by Chief Judge MICHEL. Dissenting opinion filed by Circuit Judge RADER.

MICHEL, Chief Judge.

Dane K. Fisher and Raghunath Lalgudi (collectively "Fisher")[1] appeal from the decision of the U.S. Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences ("Board") affirming the examiner's final rejection of the only pending claim of application Serial No. 09/619,643 (the "'643 application"), entitled "Nucleic Acid Molecules and Other Molecules Associated with Plants," as unpatentable for lack of utility under 35 U.S.C. § 101 and lack of enablement under 35 U.S.C. § 112, first paragraph. Ex parte Fisher, App. No. 2002-2046 (Bd. Pat. App. Int. Mar. 16, 2004) ("Board Decision"). This appeal was submitted after oral argument on May 3, 2005. Because we conclude that substantial evidence supports the Board's findings that the

---

[1] The real party in interest is Monsanto Technology LLC, which is owned by the Monsanto Company.

claimed invention lacks a specific and substantial utility and that the '643 application does not enable one of ordinary skill in the art to use the invention, we affirm.

I. BACKGROUND

A. Molecular Genetics and ESTs

The claimed invention relates to five purified nucleic acid sequences that encode proteins and protein fragments in maize plants. The claimed sequences are commonly referred to as "expressed sequence tags" or "ESTs." Before delving into the specifics of this case, it is important to understand more about the basic principles of molecular genetics and the role of ESTs.

Genes are located on chromosomes in the nucleus of a cell and are made of deoxyribonucleic acid ("DNA"). DNA is composed of two strands of nucleotides in double helix formation. The nucleotides contain one of four bases, adenine ("A"), guanine ("G"), cytosine ("C"), and thymine ("T"), that are linked by hydrogen bonds to form complementary base pairs (i.e., A-T and G-C).

When a gene is expressed in a cell, the relevant double-stranded DNA sequence is transcribed into a single strand of messenger ribonucleic acid ("mRNA"). Messenger RNA contains three of the same bases as DNA (A, G, and C), but contains uracil ("U") instead of thymine. mRNA is released from the nucleus of a cell and used by ribosomes found in the cytoplasm to produce proteins.

Complementary DNA ("cDNA") is produced synthetically by reverse transcribing mRNA. cDNA, like naturally occurring DNA, is composed of nucleotides containing the four nitrogenous bases, A, T, G, and C. Scientists routinely compile cDNA into libraries to study the kinds of genes expressed in a certain tissue at a particular point in time.

One of the goals of this research is to learn what genes and downstream proteins are expressed in a cell so as to regulate gene expression and control protein synthesis.[2]

An EST is a short nucleotide sequence that represents a fragment of a cDNA clone. It is typically generated by isolating a cDNA clone and sequencing a small number of nucleotides located at the end of one of the two cDNA strands. When an EST is introduced into a sample containing a mixture of DNA, the EST may hybridize with a portion of DNA. Such binding shows that the gene corresponding to the EST was being expressed at the time of mRNA extraction.

Claim 1 of the '643 application recites:

> A substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 5.

The ESTs set forth in SEQ ID NO: 1 through SEQ ID NO: 5 are obtained from cDNA library LIB3115, which was generated from pooled leaf tissue harvested from maize plants (RX601, Asgrow Seed Company, Des Moines, Iowa, U.S.A.) grown in the fields at Asgrow research stations. SEQ ID NO:1 through SEQ ID NO:5 consist of 429, 423, 365, 411, and 331 nucleotides, respectively. When Fisher filed the '643 application, he claimed ESTs corresponding to genes expressed from the maize pooled leaf tissue at the time of anthesis. Nevertheless, Fisher did not know the precise structure or function of either the genes or the proteins encoded for by those genes.

The '643 application generally discloses that the five claimed ESTs may be used in a variety of ways, including: (1) serving as a molecular marker for mapping the entire

---

[2] We have discussed the basic principles of molecular genetics more extensively in prior cases. See, e.g., In re Deuel, 51 F.3d 1552, 1554-56 (Fed. Cir. 1995); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1207-08 (Fed. Cir. 1991); In re O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988).

maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression; (3) providing a source for primers for use in the polymerase chain reaction ("PCR") process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.

B. Final Rejection

In a final rejection, dated September 6, 2001, the examiner rejected claim 1 for lack of utility under § 101. The examiner found that the claimed ESTs were not supported by a specific and substantial utility. She concluded that the disclosed uses were not specific to the claimed ESTs, but instead were generally applicable to any EST. For example, the examiner noted that any EST may serve as a molecular tag to isolate genetic regions. She also concluded that the claimed ESTs lacked a substantial utility because there was no known use for the proteins produced as final products resulting from processes involving the claimed ESTs. The examiner stated: "Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities."

The examiner also rejected the claimed application for lack of enablement under § 112, first paragraph. She reasoned that one skilled in the art would not know how to use the claimed ESTs because the '643 application did not disclose a specific and substantial utility for them.

On July 19, 2000, Fisher filed a notice of appeal with the Board.

C. Board Proceedings

The Board considered each of Fisher's seven potential uses but noted that Fisher focused its appeal on only two: (1) use for the identification of polymorphisms; and (2) use as probes or as a source for primers. As to the first, the Board found that the application failed to explain why the claimed ESTs would be useful in detecting polymorphisms in maize plants. Board Decision, slip op. at 14. The Board reasoned that "[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage." Id., slip op. at 15. Thus, the Board concluded that Fisher's asserted uses for the claimed ESTs tended to the "insubstantial use" end of the spectrum between a substantial and an insubstantial utility. Id.

The Board also concluded that using the claimed ESTs to isolate nucleic acid molecules of other plants and organisms, which themselves had no known utility, is not a substantial utility. Id., slip op. at 16. Specifically, the Board noted that Fisher argued that the "claimed ESTs may be useful in searching for promoters that are only active in leaves at the time of anthesis." Id. The Board found, however, that the application failed to show that the claimed ESTs would be expressed only during anthesis or that they would be capable of isolating a promoter active in maize leaves at the time of anthesis. Id., slip op. at 18.

Additionally, the Board addressed the remaining asserted utilities, highlighting in particular the use of the claimed ESTs to monitor gene expression by measuring the level of mRNA through microarray technology and to serve as molecular markers. The Board found that using the claimed ESTs in screens does not provide a specific benefit

because the application fails to provide any teaching regarding how to use the data relating to gene expression. Id., slip op. at 21. The Board analogized the facts to those in Brenner v. Manson, 383 U.S. 519 (1966), in which an applicant claimed a process of making a compound having no known use. In that case, the Supreme Court affirmed the rejection of the application on § 101 grounds. Here, the Board reasoned: "Just as the process in Brenner lacked utility because the specification did not disclose how to use the end-product, the products claimed here lack utility, because even if used in gene expression assays, the specification does not disclose how to use SEQ ID NO: 1-5 specific gene expression data." Id., slip op. at 22. The Board offered a similar rationale for the use of the claimed ESTs as molecular markers. Id., slip op. at 24. Accordingly, the Board affirmed the examiner's rejection of the '643 application for lack of utility under § 101. The Board also affirmed the examiner's rejection of the '643 application for lack of enablement under § 112, first paragraph, since the enablement rejection was made as a corollary to the utility rejection.

Fisher timely appealed. We have jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(4) and 35 U.S.C. §§ 141 and 144.

II. DISCUSSION

Whether an application discloses a utility for a claimed invention is a question of fact. In re Ziegler, 992 F.2d 1197, 1200 (Fed. Cir. 1993). We consequently review the Board's determination that the '643 application failed to satisfy the utility requirement of § 101 for substantial evidence. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000) ("Because our review of the Board's decision is confined to the factual record compiled

by the Board, we accordingly conclude that the 'substantial evidence' standard is appropriate for our review of Board factfindings.").

A. Utility

1.

Fisher asserts that the Board unilaterally applied a heightened standard for utility in the case of ESTs, conditioning patentability upon "some undefined 'spectrum' of knowledge concerning the corresponding gene function." Fisher contends that the standard is not so high and that Congress intended the language of § 101 to be given broad construction. In particular, Fisher contends that § 101 requires only that the claimed invention "not be frivolous, or injurious to the well-being, good policy, or good morals of society," essentially adopting Justice Story's view of a useful invention from Lowell v. Lewis, 15 F. Cas. 1018, 1019 (No. 8568) (C.C. Mass. 1817). Under the correct application of the law, Fisher argues, the record shows that the claimed ESTs provide seven specific and substantial uses, regardless whether the functions of the genes corresponding to the claimed ESTs are known. Fisher claims that the Board's attempt to equate the claimed ESTs with the chemical compositions in Brenner was misplaced and that several decisions in the field of pharmaceuticals, namely, Cross v. Iizuka, 753 F.2d 1040 (Fed. Cir. 1985), Nelson v. Bowler, 626 F.2d 853 (C.C.P.A. 1980), and In re Jolles, 628 F.2d 1322 (C.C.P.A. 1980), are analogous and support finding utility of the claimed ESTs. Fisher likewise argues that the general commercial success of ESTs in the marketplace confirms the utility of the claimed ESTs. Hence, Fisher avers that the Board's decision was not supported by substantial evidence and should be reversed.

The government agrees with Fisher that the utility threshold is not high, but disagrees with Fisher's allegation that the Board applied a heightened utility standard. The government contends that a patent applicant need disclose only a single specific and substantial utility pursuant to Brenner, the very standard articulated in the PTO's "Utility Examination Guidelines" ("Utility Guidelines") and followed here when examining the '643 application. It argues that Fisher failed to meet that standard because Fisher's alleged uses are so general as to be meaningless. What is more, the government asserts that the same generic uses could apply not only to the five claimed ESTs but also to any EST derived from any organism. It thus argues that the seven utilities alleged by Fisher are merely starting points for further research, not the end point of any research effort. It further disputes the importance of the commercial success of ESTs in the marketplace, pointing out that Fisher's evidence involved only databases, clone sets, and microarrays, not the five claimed ESTs. Therefore, the government contends that we should affirm the Board's decision.

Several academic institutions and biotechnology and pharmaceutical companies[3] write as amici curiae in support of the government. Like the government, they assert that Fisher's claimed uses are nothing more than a "laundry list" of research plans, each general and speculative, none providing a specific and substantial benefit in currently available form. The amici also advocate that the claimed ESTs are the objects of further research aimed at identifying what genes of unknown function are expressed during anthesis and what proteins of unknown function are encoded for by those genes.

---

[3] Amici in support of the government include Affymetrix, Inc., American College of Medical Genetics, Association of American Medical Colleges, Baxter Healthcare Corporation, Dow AgroSciences LLC, Eli Lilly and Company, Genentech, Inc., National Academy of Sciences, and the University of North Carolina School of Law.

Until the corresponding genes and proteins have a known function, the amici argue, the claimed ESTs lack utility under § 101 and are not patentable.

We agree with both the government and the amici that none of Fisher's seven asserted uses meets the utility requirement of § 101. Section 101 provides: "Whoever invents . . . any new and useful . . . composition of matter . . . may obtain a patent therefor . . . ." (Emphasis added). In Brenner, the Supreme Court explained what is required to establish the usefulness of a new invention, noting at the outset that "a simple, everyday word ["useful," as found in § 101] can be pregnant with ambiguity when applied to the facts of life." 383 U.S. at 529. Contrary to Fisher's argument that § 101 only requires an invention that is not "frivolous, injurious to the well-being, good policy, or good morals of society," the Supreme Court appeared to reject Justice Story's de minimis view of utility. Id. at 532-33 (citation omitted). The Supreme Court observed that Justice Story's definition "sheds little light on our subject," on the one hand framing the relevant inquiry as "whether the invention in question is 'frivolous and insignificant'" if narrowly read, while on the other hand "allowing the patenting of any invention not positively harmful to society" if more broadly read. Id. at 533. In its place, the Supreme Court announced a more rigorous test, stating:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

Brenner, 383 U.S. at 534-35 (emphases added). Following Brenner, our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101. See, e.g., Fujikawa v.

Wattanasin, 93 F.3d 1559, 1563 (Fed. Cir. 1996) ("Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.").

The Supreme Court has not defined what the terms "specific" and "substantial" mean per se. Nevertheless, together with the Court of Customs and Patent Appeals, we have offered guidance as to the uses which would meet the utility standard of § 101. From this, we can discern the kind of disclosure an application must contain to establish a specific and substantial utility for the claimed invention.

Courts have used the labels "practical utility" and "real world" utility interchangeably in determining whether an invention offers a "substantial" utility. Indeed, the Court of Customs and Patent Appeals stated that "'[p]ractical utility' is a shorthand way of attributing 'real-world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." Nelson, 626 F.2d at 856 (emphasis added).[4] It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.

Turning to the "specific" utility requirement, an application must disclose a use which is not so vague as to be meaningless. Indeed, one of our predecessor courts has observed "that the nebulous expressions 'biological activity' or 'biological properties'

---

[4] In Cross, this court considered the phrase "practical utility" to be synonymous with the phrase "substantial utility." 753 F.2d at 1047, n.13.

appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression 'useful for technical and pharmaceutical purposes' unsuccessfully relied upon by the appellant in In re Diedrich." In re Kirk, 376 F.2d 936, 941 (C.C.P.A. 1967). Thus, in addition to providing a "substantial" utility, an asserted use must also show that that claimed invention can be used to provide a well-defined and particular benefit to the public.

In 2001, partially in response to questions about the patentability of ESTs, the PTO issued Utility Guidelines governing its internal practice for determining whether a claimed invention satisfies § 101. See Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). The PTO incorporated these guidelines into the Manual of Patent Examining Procedure ("MPEP"). See U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure § 2107 (8th ed. 2001, rev. May 2004). The MPEP and Guidelines "are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute." Enzo Biochem v. Gen-Probe, 323 F.3d 956, 964 (Fed. Cir. 2002) (citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995)). According to the Utility Guidelines, a specific utility is particular to the subject matter claimed and would not be applicable to a broad class of invention. Manual of Patent Examining Procedure § 2107.01. The Utility Guidelines also explain that a substantial utility defines a "real world" use. In particular, "[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities." Id. Further, the Utility Guidelines discuss "research tools," a term often given to inventions used to conduct research. The PTO particularly cautions that

> [a]n assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact "useful" in a patent sense. [The PTO] must distinguish between inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm.

Id. The PTO's standards for assessing whether a claimed invention has a specific and substantial utility comport with this court's interpretation of the utility requirement of § 101.

Turning to the parties' arguments, Fisher first raises a legal issue, charging that the Board applied a heightened standard for utility in the case of ESTs. Fisher apparently bases this argument on statements made by the Board in connection with its discussion of whether the claimed ESTs can be used to identify a polymorphism. In that context, the Board stated:

> Somewhere between having no knowledge (the present circumstances) and having complete knowledge of the gene and its role in the plant's development lies the line between 'utility' and 'substantial utility.' We need not draw the line or further define it in this case because the facts in this case represent the lowest end of the spectrum, i.e., an insubstantial use.

Board Decision, slip op. at 15 (emphasis added). Fisher reads the word "spectrum" out of context, claiming that the word somehow implies the application of a higher standard for utility than required by § 101. We conclude, however, that the Board did not apply an incorrect legal standard. In its decision, the Board made reference to a "spectrum" to differentiate between a substantial utility, which satisfies the utility requirement of § 101, and an insubstantial utility, which fails to satisfy § 101. The Board plainly did not announce or apply a new test for assessing the utility of ESTs. It simply followed the Utility Guidelines and MPEP, which mandate the specific and substantial utility test set forth in Brenner. Indeed, we note that Example 9 of the PTO's "Revised Interim Utility

Guidelines Training Materials" is applicable to the facts here. See U.S. Pat. & Trademark Off., Revised Interim Utility Guidelines Training Materials 50-53 (1999), available at www.uspto.gov/web/menu/utility.pdf. In that example, a cDNA fragment disclosed as being useful as a probe to obtain the full length gene corresponding to a cDNA fragment was deemed to lack a specific and substantial utility. Additionally, the MPEP particularly explains that a claim directed to a polynucleotide disclosed to be useful as a "gene probe" or "chromosome marker," as is the case here, fails to satisfy the specific utility requirement unless a specific DNA target is also disclosed. Manual of Patent Examining Procedure § 2107.01.

Regarding the seven uses asserted by Fisher, we observe that each claimed EST uniquely corresponds to the single gene from which it was transcribed ("underlying gene"). As of the filing date of the '643 application, Fisher admits that the underlying genes have no known functions. Fisher, nevertheless, claims that this fact is irrelevant because the seven asserted uses are not related to the functions of the underlying genes. We are not convinced by this contention. Essentially, the claimed ESTs act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. The overall goal of such experimentation is presumably to understand the maize genome – the functions of the underlying genes, the identity of the encoded proteins, the role those proteins play during anthesis, whether polymorphisms exist, the identity of promoters that trigger protein expression, whether protein expression may be controlled, etc. Accordingly, the claimed ESTs are, in words of the Supreme Court, mere "object[s] of use-testing," to wit, objects upon which scientific research could be

performed with no assurance that anything useful will be discovered in the end. Brenner, 383 U.S. at 535.

Fisher compares the claimed ESTs to certain other patentable research tools, such as a microscope. Although this comparison may, on first blush, be appealing in that both a microscope and one of the claimed ESTs can be used to generate scientific data about a sample having unknown properties, Fisher's analogy is flawed. As the government points out, a microscope has the specific benefit of optically magnifying an object to immediately reveal its structure. One of the claimed ESTs, by contrast, can only be used to detect the presence of genetic material having the same structure as the EST itself. It is unable to provide any information about the overall structure let alone the function of the underlying gene. Accordingly, while a microscope can offer an immediate, real world benefit in a variety of applications, the same cannot be said for the claimed ESTs. Fisher's proposed analogy is thus inapt. Hence, we conclude that Fisher's asserted uses are insufficient to meet the standard for a "substantial" utility under § 101.

Moreover, all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world. Focusing on the two uses emphasized by Fisher at oral argument, Fisher maintains that the claimed ESTs could be used to identify polymorphisms or to isolate promoters. Nevertheless, in the face of a utility rejection, Fisher has not presented any evidence, as the Board well noted, showing that the claimed ESTs have been used in either way. That is, Fisher does not present either a single polymorphism or a single promoter,

assuming at least one of each exists, actually identified by using the claimed ESTs. Further, Fisher has not shown that a polymorphism or promoter so identified would have a "specific and substantial" use. The Board, in fact, correctly recognized this very deficiency and cited it as one of the reasons for upholding the examiner's final rejection.

With respect to the remaining asserted uses, there is no disclosure in the specification showing that any of the claimed ESTs were used as a molecular marker on a map of the maize genome. There also is no disclosure establishing that any of the claimed ESTs were used or, for that matter, could be used to control or provide information about gene expression. Significantly, despite the fact that maize leaves produce over two thousand different proteins during anthesis, Fisher failed to show that one of the claimed ESTs translates into a portion of one of those proteins. Fisher likewise did not provide any evidence showing that the claimed ESTs were used to locate genetic molecules in other plants and organisms. What is more, Fisher has not proffered any evidence showing that any such generic molecules would themselves have a specific and substantial utility. Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a "substantial" utility under § 101.

Furthermore, Fisher's seven asserted uses are plainly not "specific." Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. That is, any EST transcribed from any gene in the maize genome may be a molecular marker or a source for primers. Likewise, any EST transcribed from any gene in the maize genome may be used to measure the level of mRNA in a

tissue sample, identify the presence or absence of a polymorphism, isolate promoters, control protein expression, or locate genetic molecules of other plants and organisms. Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.

We agree with the Board that the facts here are similar to those in Brenner. There, as noted above, the applicant claimed a process for preparing compounds of unknown use. Similarly, Fisher filed an application claiming five particular ESTs which are capable of hybridizing with underlying genes of unknown function found in the maize genome. The Brenner court held that the claimed process lacked a utility because it could be used only to produce a compound of unknown use. The Brenner court stated: "We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product." 383 U.S. at 535. Applying that same logic here, we conclude that the claimed ESTs, which do not correlate to an underlying gene of known function, fail to meet the standard for utility intended by Congress.

In addition to approving of the Board's reliance on Brenner, we observe that the facts here are even more analogous to those presented in Kirk, 376 F.2d 936, and In re Joly, 376 F.2d 906 (C.C.P.A. 1967), two cases decided by our predecessor court shortly after Brenner. In Kirk, the applicant sought to patent new steroidal compounds

disclosed as having two possible utilities. First, the applicant alleged that the claimed compounds were useful for their "biological activity" because "one skilled in the art would know how to use the compounds . . . to take advantage of their presently-existing biological activity." Kirk, 376 F.2d at 939. The court rejected this claimed utility on the ground that it was not sufficiently "specific," but was instead "nebulous." Id. at 941.

Second, the applicant asserted that the claimed compounds could be used by skilled chemists as intermediates in the preparation of final steroidal compounds of unknown use. Relying on Brenner, the court reasoned:

> It seems clear that, if a process for producing a product of only conjectural use is not itself "useful" within § 101, it cannot be said that the starting materials for such a process – i.e., the presently claimed intermediates – are "useful." It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use. Nor is it enough that the product disclosed to be obtained from the intermediate belongs to some class of compounds which now is, or in the future might be, the subject of research to determine some specific use. Cf. Reiners v. Mehltretter, 236 F.2d 418, 421 [(C.C.P.A. 1956)] where compounds employed as intermediates to produce other directly useful compounds were found to be themselves useful.

Id. at 945-46 (emphasis added). Therefore, the court affirmed the Board's rejection of the claimed compounds for lack of utility.

The facts in Joly are nearly identical to the facts in Kirk. The Joly applicant filed an application claiming compounds useful as intermediates in preparing steroids that were themselves not shown or known to be useful, but that were similar in chemical structure to steroids of known pharmacological usefulness. The court adopted the reasoning of the Kirk court in its entirety and affirmed the Board's decision rejecting the claimed intermediates for failing to comply with § 101. Joly, 376 F.2d at 908-09.

Just as the claimed compounds in Kirk and Joly were useful only as intermediates in the synthesis of other compounds of unknown use, the claimed ESTs can only be used as research intermediates in the identification of underlying protein-encoding genes of unknown function. The rationale of Kirk and Joly thus applies here. In the words of the Kirk court:

> We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.

376 F.2d at 942 (emphasis added).

That the Kirk and Joly decisions involved chemical compounds, while the present case involves biological entities, does not distinguish these decisions. The rationale presented therein, having been drawn from principles set forth by the Supreme Court in Brenner, applies with equal force in the fields of chemistry and biology as well as in any scientific discipline. In Brenner, the Supreme Court was primarily concerned with creating an unwarranted monopoly to the detriment of the public:

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public. . . . This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now

> seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy.

Brenner, 383 U.S. at 535-36 (citations, quotation, and footnote omitted). Here, granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility. Thus, while Fisher's claimed ESTs may add a noteworthy contribution to biotechnology research, our precedent dictates that the '643 application does not meet the utility requirement of § 101 because Fisher does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent.

2.

Fisher's reliance on Jolles, Nelson, and Cross, cases which found utility in certain claimed pharmaceutical compounds, is misplaced. In Jolles, the applicant filed an application claiming naphthacene compounds useful in treating acute myloblastic leukemia. To support the asserted utility, the applicant presented in vivo data showing eight of the claimed compounds effectively treated tumors in a mouse model. Our predecessor court reversed the Board's affirmance of the final rejection for lack of utility, finding that the structural similarity between the compounds tested in vivo and the

remaining claimed compounds was sufficient to establish utility for the remaining claimed compounds. Jolles, 628 F.2d at 1327-28.

In Nelson, decided by the Court of Customs and Patent Appeals in the same year as Jolles, Nelson claimed prostaglandin compounds. The PTO declared an interference with an application filed by Bowler claiming the same compounds. The issue before the Board was whether Nelson had established utility for the claimed prostaglandins as smooth muscle stimulants and blood pressure modulators via in vivo and in vitro data, specifically, an in vivo rat blood pressure test and an in vitro gerbil colon smooth muscle stimulation test. The Board declined to award priority to Nelson, characterizing Nelson's tests as "rough screens, uncorrelated with actual utility [in humans]." Our predecessor court reversed, concluding that "tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use." Nelson, 626 F.2d at 856.

In Cross, decided by the Federal Circuit five years after Jolles and Nelson, Iizuka filed an application claiming thromboxane synthetase inhibitors, alleged to be useful in treating inflammation, asthma, hypertension, and other ailments. When Cross filed an application claiming the same compounds two months after Iizuka, the PTO declared an interference. The dispositive issue concerned whether Iizuka's Japanese priority application disclosed utility for the claimed inhibitors. The Board concluded that it offered a sufficient disclosure based upon in vitro data showing strong inhibitory action for thromboxane synthetase for structurally-similar compounds in human or bovine platelet microsomes. We affirmed, reasoning:

> Opinions of our predecessor court have recognized the fact that pharmacological testing of animals is a screening procedure for testing

> new drugs for practical utility. This in vivo testing is but an intermediate link in a screening chain which may eventually lead to the use of the drug as a therapeutic agent in humans. We perceive no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question. Successful in vitro testing will marshal resources and direct the expenditure of effort to further in vivo testing of the most potent compounds, thereby providing an immediate benefit to the public, analogous to the benefit provided by the showing of an in vivo utility.

Cross, 753 F.2d at 1050 (citations omitted).

The facts in these three cases are readily distinguishable from the facts here. In Jolles, Nelson, and Cross, the applicants disclosed specific pharmaceutical uses in humans for the claimed compounds and supported those uses with specific animal test data, in vitro, in vivo, or both. In contrast, Fisher disclosed a variety of asserted uses for the claimed ESTs, but failed to present any evidence – test data, declaration, deposition testimony, or otherwise – to support those uses as presently beneficial and hence practical. Fisher did not show that even one of the claimed ESTs had been tested and successfully aided in identifying a polymorphism in the maize genome or in isolating a single promoter that could give clues about protein expression. Adopting the language of the Cross court, the alleged uses in Jolles, Nelson, and Cross were not "nebulous expressions, such as 'biological activity' or 'biological properties' [alleged in the application in Kirk]," that "convey little explicit indication regarding the utility of a compound." Cross, 753 F.2d at 1048. Instead, the alleged uses in those cases gave a firm indication of the precise uses to which the claimed compounds could be put. For example, in Nelson, the claimed prostaglandins could be used to stimulate smooth muscle or modulate blood pressure in humans as shown by both in vivo and in vitro animal data. Hence, the Jolles, Nelson, and Cross courts concluded that the claimed

pharmaceutical compounds satisfied the specific and substantial utility requirements of § 101. We cannot reach that same conclusion here. Fisher's laundry list of uses, like the terms "biological activity" or "biological properties" alleged in Kirk, are nebulous, especially in the absence of any data demonstrating that the claimed ESTs were actually put to the alleged uses.

Fisher's reliance on the commercial success of general EST databases is also misplaced because such general reliance does not relate to the ESTs at issue in this case. Fisher did not present any evidence showing that agricultural companies have purchased or even expressed any interest in the claimed ESTs. And, it is entirely unclear from the record whether such business entities ever will. Accordingly, while commercial success may support the utility of an invention, it does not do so in this case. See Raytheon Co. v. Roper Corp., 724 F.2d 951, 959 (Fed. Cir. 1983) (stating that proof of a utility may be supported when a claimed invention meets with commercial success).

3.

As a final matter, we observe that the government and its amici express concern that allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the "useful Arts" and "Science." See U.S. Const. art. I, § 8, cl. 8. The government and its amici point out that allowing EST claims like Fisher's would give rise to multiple patents, likely owned by several different companies, relating to the same underlying gene and expressed protein. Such a situation, the government and amici predict, would result in an unnecessarily convoluted licensing environment for those interested in researching that gene and/or protein.

The concerns of the government and amici, which may or may not be valid, are not ones that should be considered in deciding whether the application for the claimed ESTs meets the utility requirement of § 101. The same may be said for the resource and managerial problems that the PTO potentially would face if applicants present the PTO with an onslaught of patent applications directed to particular ESTs. Congress did not intend for these practical implications to affect the determination of whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. They are public policy considerations which are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law. Under Title 35, an applicant is entitled to a patent if his invention is new, useful, nonobvious, and his application adequately describes the claimed invention, teaches others how to make and use the claimed invention, and discloses the best mode for practicing the claimed invention. What is more, when Congress enacted § 101, it indicated that "anything under the sun that is made by man" constitutes potential subject matter for a patent. S. Rep. No. 82-1979, at 7 (1985). Policy reasons aside, because we conclude that the utility requirement of § 101 is not met, we hold that Fisher is not entitled to a patent for the five claimed ESTs.

B. Enablement

Fisher asserts that we should reverse the enablement rejection upheld by the Board since the Board made it contingent upon the utility rejection, which Fisher argues was not supported by substantial evidence for reasons analyzed above. The government argues to the contrary, asserting that claim 1 of the '643 application cannot

be enabled because the claimed ESTs were not disclosed as having a specific and substantial utility. We agree with the government. It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101.

> The how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.

Ziegler, 992 F.2d at 1200-01 (citations omitted); see also Kirk, 376 F.2d at 942 ("Necessarily, compliance with § 112 requires a description of how to use presently useful inventions, otherwise an applicant would anomalously be required to teach how to use a useless invention."); In re Brana, 51 F.3d 1560, 1564 (Fed. Cir. 1995) ("Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it."); Manual of Patent Examining Procedure § 2107.01. Here, in light of our conclusion that the Board's decision with respect to utility applied the correct legal standard and was supported by substantial evidence, we conclude that Fisher failed to satisfy the enablement requirement. Consequently, we leave undisturbed the enablement rejection of the '643 application under § 112, first paragraph.

III. CONCLUSION

We conclude that substantial evidence supports the Board's findings that each of the five claimed ESTs lacksa specific and substantial utility and that they are not enabled. Accordingly, the Board's decision affirming the final rejection of claim 1 of the '643 patent for lack of utility under § 101 and lack of enablement under § 112, first paragraph, is affirmed.

AFFIRMED

United States Court of Appeals for the Federal Circuit

04-1465
(Serial No. 09/619,643)

IN RE DANE K. FISHER and RAGHUNATH V. LALGUDI

RADER, Circuit Judge, dissenting.

This court today determines that expressed sequence tags (ESTs) do not satisfy 35 U.S.C. § 101 unless there is a known use for the genes from which each EST is transcribed. While I agree that an invention must demonstrate utility to satisfy § 101, these claimed ESTs have such a utility, at least as research tools in isolating and studying other molecules. Therefore, I respectfully dissent.

Several, if not all, of Fisher's asserted utilities claim that ESTs function to study other molecules. In simple terms, ESTs are research tools. Admittedly ESTs have use only in a research setting. However, the value and utility of research tools generally is beyond question, even though limited to a laboratory setting. See U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure (MPEP) § 2107.01 at 2100-33 (8th ed. 2001, rev. Feb. 2003) ("Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds)."). Thus, if the claimed ESTs qualify as research tools, then they have a "specific" and "substantial" utility sufficient for § 101. If these ESTs do not enhance research, then Brenner v. Manson, 383 U.S. 519 (1966) (involving the patentability of methods for producing compounds having no known use) controls and erects a § 101 bar for lack of utility. For

the following reasons, these claimed ESTs are more akin to patentable research tools than to the unpatentable methods in Brenner.

In Brenner, the Court confronted a growing conflict between this court's predecessor, the Court of Customs and Patent Appeals (CCPA), and the Patent Office over the patentability of methods of producing compounds with no known use. This conflict began with In re Nelson, 280 F.2d 172 (CCPA 1960), the first in a series of cases wherein the CCPA reversed several Patent Office utility rejections. Brenner, 383 U.S. at 530. Brenner put an end to these cases because, in the 1960s, the Court could not distinguish between denying patents to compounds with no known use and denying patents to methods of producing those useless compounds. The Court commented:

> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.

Id. at 535. This court's predecessor later extended Brenner to bar patents on compounds as intermediates in the preparation of other compounds having no known use. See In re Kirk, 376 F.2d 936 (CCPA 1967) (rejecting intermediaries for steroids with no known use). These cases, however, share a common underpinning - a method of producing a compound with no known use has no more benefit to society than the useless compound itself.

This case is very different. Unlike the methods and compounds in Brenner and Kirk, Fisher's claimed EST's *are* beneficial to society. As an example, these research tools "may help scientists to isolate the particular underlying protein-encoding genes . . . [with the] overall goal of such experimentation . . . presumably [being] to understand the

maize genome[.]" Majority Opinion, slip op. at 13. They also can serve as a probe introduced into a sample tissue to confirm "that the gene corresponding to the EST was being expressed in the sample tissue at the time of mRNA extraction." Id., slip op. at 3.

These research tools are similar to a microscope; both take a researcher one step closer to identifying and understanding a previously unknown and invisible structure. Both supply information about a molecular structure. Both advance research and bring scientists closer to unlocking the secrets of the corn genome to provide better food production for the hungry world. If a microscope has § 101 utility, so too do these ESTs.

The Board and this court acknowledge that the ESTs perform a function, that they have a utility, but proceed quickly to a value judgment that the utility would not produce enough valuable information. The Board instead complains that the information these ESTs supply is too "insubstantial" to merit protection. Yet this conclusion denies the very nature of scientific advance. Science always advances in small incremental steps. While acknowledging the patentability of research tools generally (and microscopes as one example thereof), this court concludes with little scientific foundation that these ESTs do not qualify as research tools because they do not "offer an immediate, real world benefit" because further research is required to understand the underlying gene. This court further faults the EST research for lacking any "assurance that anything useful will be discovered in the end." These criticisms would foreclose much scientific research and many vital research tools. Often scientists embark on research with no assurance of success and knowing that even success will demand "significant additional research."

Nonetheless, this court, oblivious to the challenges of complex research, discounts these ESTs because it concludes (without scientific evidence) that they do not supply enough information. This court reasons that a research tool has a "specific" and "substantial" utility *only* if the studied object is readily understandable using the claimed tool - that no further research is required. Surely this cannot be the law. Otherwise, only the final step of a lengthy incremental research inquiry gets protection.

Even with a microscope, significant additional research is often required to ascertain the particular function of a "revealed" structure. To illustrate, a cancerous growth, magnified with a patented microscope, can be identified and distinguished from other healthy cells by a properly trained doctor or researcher. But even today, the scientific community still does not fully grasp the reasons that cancerous growths increase in mass and spread throughout the body,[1] or the nature of compounds that interact with them, or the interactions of environmental or genetic conditions that contribute to developing cancer. Significant additional research is required to answer these questions. Even with answers to these questions, the cure for cancer will remain in the distance. Yet the microscope still has "utility" under § 101. Why? Because it takes the researcher one step closer to answering these questions. Each step, even if

---

[1] ESTs have already been used to advance cancer research well beyond what is achievable using microscopes alone. See Andy J. Minn, Genes That Mediate Breast Cancer Metastisis To Lung, Nature, July 28, 2005 at 518-24 (discussing research to identify genes that mark and mediate breast cancer metastisis to the lung).

small in isolation, is nonetheless a benefit to society sufficient to give a viable research tool "utility" under § 101. In fact, experiments that fail still serve to eliminate some possibilities and provide information to the research process.

The United States Patent Office, above all, should recognize the incremental nature of scientific endeavor. Yet, in the interest of easing its administrative load, the Patent Office will eliminate some research tools as providing "insubstantial" advances. How does the Patent Office know which "insubstantial" research step will contribute to a substantial breakthrough in genomic study? Quite simply, it does not.

In addition, this court faults Fisher for not presenting evidence of utility showing that the claimed ESTs "have been used in the real world." To the contrary, this court misapprehended the proper procedure. Fisher asserted seven different utilities. The Board rejected two of these assertions outright as "insubstantial." See Ex parte Fisher, App. No. 2002-2046, slip. op at 14-16 (Bd. Pat. App. and Int. 2004) (acknowledging that the ESTs may be able to detect "the absence of a polymorphism" and "to isolate nucleic acid molecules of other plants and organisms[,]" but finding such utilities are not "substantial" even if the ESTs can perform them). This summary dismissal deprived Fisher of any chance to proffer evidence. Rather than fault Fisher for not presenting evidence it was prevented from offering, this court should instead observe that the Board did not satisfy its burden of challenging Fisher's presumptively correct assertion that the ESTs were *capable* of performing those functions. See MPEP § 2107.02(IV) at 2100-40 (noting that the initial burden is on the office to establish a prima facie case as to lack of utility and to provide evidentiary support thereof); In re Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995) (where an applicant has asserted utility in the disclosure, the

Patent Office has the initial burden of challenging this presumptively correct assertion of utility).

Abandoning the proper legal procedure, the Board reasoned that the molecules studied with these ESTs showed no particular use, therefore the ESTs themselves also lacked a utility. In so ruling, the Board did not reject Fisher's utilities on the basis that the ESTs were *unable to perform* the purported utilities. Thus, the Board did not establish a prima facie challenge to the ESTs' ability to perform these two utilities. Without anything to rebut, Fisher had no obligation or opportunity to provide evidence in rebuttal. Thus, I respectfully disagree with this court's conclusion that the Board's decision can be affirmed on the basis that Fisher did not supply evidence of the ESTs' ability to perform the asserted utilities.

In truth, I have some sympathy with the Patent Office's dilemma. The Office needs some tool to reject inventions that may advance the "useful arts" but not sufficiently to warrant the valuable exclusive right of a patent. The Patent Office has seized upon this utility requirement to reject these research tools as contributing "insubstantially" to the advance of the useful arts. The utility requirement is ill suited to that task, however, because it lacks any standard for assessing the state of the prior art and the contributions of the claimed advance. The proper tool for assessing sufficient contribution to the useful arts is the obviousness requirement of 35 U.S.C. § 103. Unfortunately this court has deprived the Patent Office of the obviousness requirement for genomic inventions. See In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995); Martin J. Adelman et al., Patent Law, 517 (West Group 1998) (commenting that scholars have been critical of Deuel, which "overly favored patent applicants in biotech by adopting an

overly lax nonobviousness standard." (citing Anita Varma & David Abraham, DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market, 9 Harv. J. L. & Tech. 53 (1996))); Philippe Ducor, The Federal Circuit and In re Deuel: Does §103 apply to Naturally Occurring DNA?, 77 J. Pat. & Trademark Off. Soc'y 871, 883 (Nov. 1995) ("The Court of Appeals for the Federal Circuit could have formulated its opinion in only one sentence: '35 U.S.C. § 103 does not apply to newly retrieved natural DNA sequences.'"); Philippe Ducor, Recombinant Products and Nonobviousness: A Typology, 13 Santa Clara Computer and High Tech. L.J. 1, 44-45 (Feb. 1997) ("This amounts to a practical elimination of the requirement for nonobviousness for these products, even when all the information necessary to discover them is previously available."); see also over fifty additional articles critical of Deuel in the "Citing References" tab for Deuel on Westlaw. Nonetheless, rather than distort the utility test, the Patent Office should seek ways to apply the correct test, the test used world wide for such assessments (other than in the United States), namely inventive step or obviousness.

Thus, for the foregoing reasons, I would find that Fisher's asserted utilities qualify the claimed ESTs as research tools useful in the study of other molecules. Because research tools provide a cognizable benefit to society, much like a microscope, the ESTs claimed here have "utility" under § 101. In addition, the enablement rejection should also be reversed because it was a consequence of the finding of lack of utility.